

## Complete Summary

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### GUIDELINE TITLE

Practice parameter: the diagnostic evaluation and treatment of trigeminal neuralgia (an evidence-based review). Report of the Quality Standards Subcommittee of the American Academy of Neurology and the European Federation of Neurological Societies.

### BIBLIOGRAPHIC SOURCE(S)

Gronseth G, Cruccu G, Alksne J, Argoff C, Brainin M, Burchiel K, Nurmikko T, Zakrzewska JM. Practice Parameter: The diagnostic evaluation and treatment of trigeminal neuralgia (an evidence-based review). Report of the Quality Standards Subcommittee of the American Academy of Neurology and the European Federation of Neurological Societies. Neurology 2008 Oct 7;71(15):1183-90. [40 references] [PubMed](#)

### GUIDELINE STATUS

This is the current release of the guideline.

### \*\* REGULATORY ALERT \*\*

### FDA WARNING/REGULATORY ALERT

**Note from the National Guideline Clearinghouse:** This guideline references a drug(s)/intervention(s) for which important revised regulatory and/or warning information has been released.

- [December 12, 2007, Carbamazepine](#): The U.S. Food and Drug Administration (FDA) has provided recommendations for screening that should be performed on specific patient populations before starting treatment with carbamazepine.

### COMPLETE SUMMARY CONTENT

\*\* REGULATORY ALERT \*\*

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis

RECOMMENDATIONS

EVIDENCE SUPPORTING THE RECOMMENDATIONS

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

QUALIFYING STATEMENTS

IMPLEMENTATION OF THE GUIDELINE

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

## SCOPE

### DISEASE/CONDITION(S)

- Trigeminal neuralgia (TN)
- Classic TN (CTN)
- Symptomatic TN (STN)

### GUIDELINE CATEGORY

Diagnosis  
Evaluation  
Screening  
Treatment

### CLINICAL SPECIALTY

Family Practice  
Internal Medicine  
Neurological Surgery  
Neurology  
Pharmacology

### INTENDED USERS

Physicians

### GUIDELINE OBJECTIVE(S)

- To perform an evidence-based review of the diagnosis and treatment of trigeminal neuralgia (TN) and make evidence-based recommendations
- To address the following TN diagnostic questions:
  - How often does routine neuroimaging (computed tomography [CT], magnetic resonance imaging [MRI]) identify a structural cause of TN (excluding vascular contact with compression of the fifth cranial nerve)?
  - Which clinical or laboratory features accurately identify patients with symptomatic TN (STN)?
  - For patients with classic TN (CTN), does high-resolution MRI accurately identify patients with neurovascular compression?
- To address the following TN pharmacologic questions:
  - Which drugs effectively treat CTN?
  - Which drugs effectively treat STN?
  - Is there evidence of efficacy of intravenous drugs in acute exacerbations of TN?
- To address the following TN surgical questions:
  - When should surgery be offered?

- Which surgical technique gives the longest pain-free period with the fewest complications and good quality of life?
- Which surgical techniques should be used in patients with multiple sclerosis?

## **TARGET POPULATION**

Patients with trigeminal neuralgia

## **INTERVENTIONS AND PRACTICES CONSIDERED**

### **Diagnosis/Evaluation**

1. Routine neuroimaging (computed tomography [CT], magnetic resonance imaging [MRI])
2. Identification of patients with symptomatic trigeminal neuralgia (STN) through clinical examination
3. Electrophysiology studies (measurement of trigeminal reflexes)
4. Use of high-resolution MRI to identify neurovascular compression (considered but not recommended)

### **Treatment**

1. Carbamazepine
2. Oxcarbazepine
3. Baclofen
4. Lamotrigine
5. Pimozide
6. Percutaneous procedures on the Gasserian ganglion
7. Gamma knife surgery
8. Microvascular decompression
9. Topical ophthalmic anesthesia (specifically not recommended)

## **MAJOR OUTCOMES CONSIDERED**

- Diagnostic yields of imaging studies
- Diagnostic accuracy of assessing clinical features for predicting risk of symptomatic trigeminal neuralgia (STN)
- Diagnostic accuracy of measuring trigeminal reflexes and trigeminal evoked potentials for identifying patients with STN
- Sensitivity and specificity of high-resolution magnetic resonance imaging (MRI) to identify neurovascular compression
- Effectiveness of drug treatment for reducing pain
- Effectiveness of surgery for reducing pain and improving quality of life
- Adverse and side effects of pharmacological therapies
- Complications of surgery
- Quality of life
- Mortality

## METHODOLOGY

### METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)  
Hand-searches of Published Literature (Secondary Sources)  
Searches of Electronic Databases

### DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The American Academy of Neurology (AAN) and European Federation of Neurological Societies (EFNS) assembled a panel of experts who searched MEDLINE, EMBASE, and the Cochrane library. Searches extended from the time of database inception to December 2007. All searches used the following synonyms for TN: trigeminal neuralgia, tic douloureux, facial pain, or trigeminal neuropathy. The primary search was supplemented by a secondary search using the bibliography of retrieved articles and knowledge from the panel. Only full-length original communications were accepted. Inclusion criteria were as follows: relevant to the clinical questions, limited to human subjects, randomized controlled trials, case control, cohort studies, case series >6, or meta-analysis. Abstracts, reviews, and studies with undocumented or unstated mention of improvement were excluded.

### NUMBER OF SOURCE DOCUMENTS

47

### METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

### RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

#### Classification of Evidence for Rating of a Screening Article

**Class I:** A statistical, population-based sample of patients studied at a uniform point in time (usually early) during the course of the condition. All patients undergo the intervention of interest. The outcome, if not objective, is determined in an evaluation that is masked to the patients' clinical presentations.

**Class II:** A statistical, non-referral-clinic-based sample of patients studied at a uniform point in time (usually early) during the course of the condition. Most patients undergo the intervention of interest. The outcome, if not objective, is determined in an evaluation that is masked to the patients' clinical presentations.

**Class III:** A sample of patients studied during the course of the condition. Some patients undergo the intervention of interest. The outcome, if not objective, is determined in an evaluation by someone other than the treating physician.

**Class IV:** Expert opinion, case reports or any study not meeting criteria for Class I to III.

### **Classification of Evidence for Rating of a Diagnostic Article**

**Class I:** Evidence provided by a prospective study in a broad spectrum of persons with the suspected condition, using a reference (gold) standard for case definition, where test is applied in a blinded evaluation, and enabling the assessment of appropriate tests of diagnostic accuracy. All patients undergoing the diagnostic test have the presence or absence of the disease determined.

**Class II:** Evidence provided by a prospective study of a narrow spectrum of persons with the suspected condition, or a well designed retrospective study of a broad spectrum of persons with an established condition (by "gold standard") compared to a broad spectrum of controls, where test is applied in a blinded evaluation, and enabling the assessment of appropriate tests of diagnostic accuracy.

**Class III:** Evidence provided by a retrospective study where either persons with the established condition or controls are of a narrow spectrum, and where the reference standard, if not objective, is applied by someone other than the person that performed the test.

**Class IV:** Any design where test is not applied in an independent evaluation OR evidence provided by expert opinion alone or in descriptive case series (without controls).

### **Classification of Evidence for Rating of a Therapeutic Article**

**Class I:** Prospective, randomized, controlled clinical trial with masked outcome assessment, in a representative population. The following are required:

- a. Concealed allocation
- b. Primary outcome(s) clearly defined
- c. Exclusion/inclusion criteria clearly defined
- d. Adequate accounting for drop-outs and cross-overs with numbers sufficiently low to have minimal potential for bias
- e. Relevant baseline characteristics are presented and substantially equivalent among treatment groups or there is appropriate statistical adjustment for differences.

**Class II:** Prospective matched group cohort study in a representative population with masked outcome assessment that meets a-e above OR a randomized controlled trial in a representative population that lacks one criteria a-d.

**Class III:** All other controlled trials (including well-defined natural history controls or patients serving as own controls) in a representative population, where outcome is independently assessed, or independently derived by objective outcome measurement.\*

**Class IV:** Evidence from uncontrolled studies, case series, case reports, or expert opinion.

\*Objective outcome measurement: an outcome measure that is unlikely to be affected by an observer's (patient, treating physician, investigator) expectation or bias (e.g., blood tests, administrative outcome data).

## **METHODS USED TO ANALYZE THE EVIDENCE**

Systematic Review with Evidence Tables

## **DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE**

Panel members reviewed abstracts and titles for relevance. Two panel members reviewed papers meeting inclusion criteria. An additional panel member arbitrated disagreements. The risk of bias was determined using the classification of evidence for each study (Classes I–IV; see "Rating Scheme for the Strength of the Evidence").

## **METHODS USED TO FORMULATE THE RECOMMENDATIONS**

Other

## **DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS**

Not stated

## **RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS**

### **Classification of Recommendations**

**Level A** = Established as effective, ineffective, or harmful (or established as useful/predictive or not useful/predictive) for the given condition in the specified population. (Level A rating requires at least two consistent Class I studies.)\*\*

**Level B** = Probably effective, ineffective, or harmful (or probably useful/predictive or not useful/predictive) for the given condition in the specified population. (Level B rating requires at least one Class I study or at least two consistent Class II studies.)

**Level C** = Possibly effective, ineffective, or harmful (or possibly useful/predictive or not useful/predictive) for the given condition in the specified population. (Level C rating requires at least one Class II study or two consistent Class III studies.)

**Level U** = Data inadequate or conflicting; given current knowledge, treatment (test, predictor) is unproven. (Studies not meeting criteria for Class I–Class III.)

\*\*In exceptional cases, one convincing Class I study may suffice for an "A" recommendation if 1) all criteria are met, 2) the magnitude of effect is large (relative rate improved outcome >5 and the lower limit of the confidence interval is <2).

## COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

## METHOD OF GUIDELINE VALIDATION

External Peer Review  
Internal Peer Review

## DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

This guideline was approved by the Quality Standards Subcommittee on February 8, 2008; by the Practice Committee on March 20, 2008; and by the American Academy of Neurology Board of Directors on June 30, 2008.

## RECOMMENDATIONS

### MAJOR RECOMMENDATIONS

Definitions of the classification of screening evidence (Classes I–IV), classification of therapeutic evidence (Classes I–IV), and strength of recommendations (A, B, C, U) are provided at the end of the "Major Recommendations" field.

For patients with trigeminal neuralgia (TN), routine imaging may be considered to identify symptomatic TN (STN) (**Level C**).

The presence of trigeminal sensory deficits or bilateral involvement of the trigeminal nerves should be considered useful to identify patients with STN. However, because of poor specificity, the absence of these features is not useful for excluding STN (**Level B**).

Measuring trigeminal reflexes in a qualified electrophysiologic laboratory should be considered useful for distinguishing STN from classic TN (CTN) (**Level B**).

Younger age at onset, involvement of the first division of the trigeminal nerve, unresponsiveness to treatment, and abnormal trigeminal evoked potentials should be disregarded as useful for accurately identifying patients with STN (**Level B**).

To control pain in patients with TN: carbamazepine should be offered (**Level A**), oxcarbazepine should be considered (**Level B**), baclofen, lamotrigine, and pimozide may be considered (**Level C**), and topical ophthalmic anesthesia should not be considered (**Level B**).

For patients with TN refractory to medical therapy: early surgical therapy may be considered (**Level C**), and percutaneous procedures on the Gasserian ganglion, gamma knife, and microvascular decompression may be considered (**Level C**).

### Definitions:

## **Classification of Evidence for Rating of a Screening Article**

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**Class II:** Evidence provided by a prospective study of a narrow spectrum of persons with the suspected condition, or a well designed retrospective study of a broad spectrum of persons with an established condition (by "gold standard") compared to a broad spectrum of controls, where test is applied in a blinded evaluation, and enabling the assessment of appropriate tests of diagnostic accuracy.

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- b. Primary outcome(s) clearly defined
- c. Exclusion/inclusion criteria clearly defined



- d. Adequate accounting for drop-outs and cross-overs with numbers sufficiently low to have minimal potential for bias
- e. Relevant baseline characteristics are presented and substantially equivalent among treatment groups or there is appropriate statistical adjustment for differences.

**Class II:** Prospective matched group cohort study in a representative population with masked outcome assessment that meets a-e above OR a randomized controlled trial in a representative population that lacks one criteria a-d.

**Class III:** All other controlled trials (including well-defined natural history controls or patients serving as own controls) in a representative population, where outcome is independently assessed, or independently derived by objective outcome measurement.\*

**Class IV:** Evidence from uncontrolled studies, case series, case reports, or expert opinion.

\*Objective outcome measurement: an outcome measure that is unlikely to be affected by an observer's (patient, treating physician, investigator) expectation or bias (e.g., blood tests, administrative outcome data).

## Classification of Recommendations

**Level A** = Established as effective, ineffective, or harmful (or established as useful/predictive or not useful/predictive) for the given condition in the specified population. (Level A rating requires at least two consistent Class I studies.)\*\*

**Level B** = Probably effective, ineffective, or harmful (or probably useful/predictive or not useful/predictive) for the given condition in the specified population. (Level B rating requires at least one Class I study or at least two consistent Class II studies.)

**Level C** = Possibly effective, ineffective, or harmful (or possibly useful/predictive or not useful/predictive) for the given condition in the specified population. (Level C rating requires at least one Class II study or two consistent Class III studies.)

**Level U** = Data inadequate or conflicting; given current knowledge, treatment (test, predictor) is unproven. (Studies not meeting criteria for Class I–Class III.)

\*\*In exceptional cases, one convincing Class I study may suffice for an "A" recommendation if 1) all criteria are met, 2) the magnitude of effect is large (relative rate improved outcome >5 and the lower limit of the confidence interval is <2).

## CLINICAL ALGORITHM(S)

None provided

## EVIDENCE SUPPORTING THE RECOMMENDATIONS

## TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

## **BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS**

### **POTENTIAL BENEFITS**

Appropriate diagnostic evaluation and treatment of trigeminal neuralgia

### **POTENTIAL HARMS**

- Carbamazepine is sometimes poorly tolerated and severe adverse events have been reported.
- Sensory loss after percutaneous procedures is present in almost half of patients. Less than 6% develop troublesome dysesthesias. The incidence of anesthesia dolorosa is around 4%. Postoperatively, 12% of patients report a discomfort described as burning, heavy, aching, or tiring. Corneal numbness, with the risk of keratitis, occurs in 4% of patients. Problems with other cranial nerves are uncommon, and the major perioperative complication is meningitis, mainly aseptic (0.2%). Up to 50% of patients undergoing balloon compression suffer temporary and rarely chronic masticatory problems. Mortality is extremely low.
- After gamma knife surgery, studies report sensory complications in some patients; complications include facial numbness, troublesome sensory loss, and paresthesias. There have been no reports of complications unrelated to the trigeminal nerve.
- The average mortality associated with microvascular decompression is 0.2%. Up to 4% of patients incur major problems such as cerebrospinal fluid leaks, infarcts, or hematomas. Aseptic meningitis is the most common complication (occurring in 11% of patients). Diplopia is often transient and facial weakness is rare. Sensory loss occurs in 7% of patients. The major long-term complication is hearing loss which can occur in as many as 10% of patients.

## **QUALIFYING STATEMENTS**

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This statement is provided as an educational service of the American Academy of Neurology. It is based on an assessment of current scientific and clinical information. It is not intended to include all possible proper methods of care for a particular neurologic problem or all legitimate criteria for choosing to use a specific procedure. Neither is it intended to exclude any reasonable alternative methodologies. The AAN recognizes that specific patient care decisions are the prerogative of the patient and the physician caring for the patient, based on all of the circumstances involved. The clinical context section is made available in order to place the evidence-based guideline into perspective with current practice habits and challenges. No formal practice recommendations should be inferred.

## IMPLEMENTATION OF THE GUIDELINE

### DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

### IMPLEMENTATION TOOLS

Patient Resources  
Quick Reference Guides/Physician Guides  
Resources  
Slide Presentation  
Staff Training/Competency Material

For information about [availability](#), see the "Availability of Companion Documents" and "Patient Resources" fields below.

## INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

### IOM CARE NEED

Living with Illness

### IOM DOMAIN

Effectiveness  
Patient-centeredness

## IDENTIFYING INFORMATION AND AVAILABILITY

### BIBLIOGRAPHIC SOURCE(S)

Gronseth G, Cruccu G, Alksne J, Argoff C, Brainin M, Burchiel K, Nurmikko T, Zakrzewska JM. Practice Parameter: The diagnostic evaluation and treatment of trigeminal neuralgia (an evidence-based review). Report of the Quality Standards Subcommittee of the American Academy of Neurology and the European Federation of Neurological Societies. Neurology 2008 Oct 7;71(15):1183-90. [40 references] [PubMed](#)

### ADAPTATION

Not applicable: The guideline was not adapted from another source.

### DATE RELEASED

2008 Oct 7

### GUIDELINE DEVELOPER(S)

American Academy of Neurology - Medical Specialty Society  
European Federation of Neurological Societies - Medical Specialty Society

## **SOURCE(S) OF FUNDING**

American Academy of Neurology (AAN)

## **GUIDELINE COMMITTEE**

Quality Standards Subcommittee

## **COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE**

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*Quality Standards Subcommittee Members:* Jacqueline French, MD, FAAN (*Chair*); Charles E. Argoff, MD; Eric Ashman, MD; Stephen Ashwal, MD, FAAN (*Ex-officio*); Christopher Bever, Jr., MD, MBA, FAAN; John D. England, MD, FAAN; Gary Franklin, MD, MPH, FAAN (*Ex-officio*); Deborah Hirtz, MD, FAAN (*Ex-officio*); Robert G. Holloway, MD, MPH, FAAN; Donald J. Iverson, MD, FAAN; Steven R. Messé, MD; Leslie A. Morrison, MD; James C. Stevens, MD, FAAN (*Ex-officio*); David J. Thurman, MD, MPH (*Ex-officio*); Dean M. Wingerchuk, MD, MSc, FRCP(C); Theresa A. Zesiewicz, MD, FAAN

## **FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST**

The American Academy of Neurology (AAN) is committed to producing independent, critical and truthful clinical practice guidelines (CPGs). Significant efforts are made to minimize the potential for conflicts of interest to influence the recommendations of this CPG. To the extent possible, the AAN keeps separate those who have a financial stake in the success or failure of the products appraised in the CPGs and the developers of the guidelines. Conflict of interest forms were obtained from all authors and reviewed by an oversight committee prior to project initiation. AAN limits the participation of authors with substantial conflicts of interest. The AAN forbids commercial participation in, or funding of, guideline projects. Drafts of the guideline have been reviewed by at least three AAN committees, a network of neurologists, *Neurology* peer reviewers and representatives from related fields. The AAN Guideline Author Conflict of Interest Policy can be viewed at [www.aan.com](http://www.aan.com).

The authors report the following conflicts of interest: Dr. Gronseth has received speaker honoraria from Boehringer Ingelheim, Pfizer, and GlaxoSmithKline, and has been compensated by Ortho-McNeil for serving on a safety monitoring committee; Dr. Cruccu has given lectures for Pfizer and estimates 5% of his clinical effort is spent on trigeminal reflex testing; Dr. Alksne estimates 10% of his clinical effort is spent on surgery for trigeminal neuralgia; Dr. Argoff estimates 25% of his clinical effort is spent on Medtronic Pump, 25% on trigger point injections, 20% on epidural steroid injections, and 30% on botulinum toxin injections; Dr. Brainin has nothing to disclose; Dr. Burchiel holds equity in

Medtronic, Boston Scientific, and Pfizer; Dr. Nurmikko holds financial interests in Boehringer Ingelheim, Pfizer UK, Grunenthal, Sanofi Pasteur MSD, and UCB/Schwarz Pharma; Dr. Nurmikko estimates 10% of his clinical effort is spent on MRI; Dr. Zakrzewska holds financial interests in UCB Pharma and has received research support from the Bupa Foundation for decision analysis in trigeminal neuralgia.

## **GUIDELINE STATUS**

This is the current release of the guideline.

## **GUIDELINE AVAILABILITY**

Electronic copies: A list of American Academy of Neurology (AAN) guidelines, along with a link to a Portable Document Format (PDF) file for this guideline, is available at the [AAN Web site](#).

Print copies: Available from the AAN Member Services Center, (800) 879-1960, or from AAN, 1080 Montreal Avenue, St. Paul, MN 55116.

## **AVAILABILITY OF COMPANION DOCUMENTS**

The following are available:

- Trigeminal neuralgia. AAN summary of evidence-based guideline for clinicians. St. Paul (MN): American Academy of Neurology. 2008. 2 p. Available in Portable Document Format (PDF) from the [AAN Web site](#).
- Practice parameter: the diagnostic evaluation and treatment of trigeminal neuralgia (an evidence-based review). Slide presentation. 2008. 57 p. Available from the [AAN Web site](#).
- Practice parameter: the diagnostic evaluation and treatment of trigeminal neuralgia (an evidence-based review). Case study and coding. 2008. 3 p. Available from the [AAN Web site](#).
- Practice parameter: the diagnostic evaluation and treatment of trigeminal neuralgia (an evidence-based review). Podcast. 2008. Available from the [AAN Web site](#).
- AAN guideline development process [online]. St. Paul (MN): American Academy of Neurology. Available from the [AAN Web site](#).

## **PATIENT RESOURCES**

The following is available:

- Trigeminal neuralgia. AAN summary of evidence-based guideline for patients and their families. St. Paul (MN): American Academy of Neurology (AAN). 2008. 2 p.

Electronic copies: Available in Portable Document Format (PDF) from the [AAN Web site](#).

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

## **NGC STATUS**

This summary was completed by ECRI Institute on September 23, 2008. This summary was completed by ECRI Institute on November 10, 2008. The information was verified by the guideline developer on December 11, 2008.

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